



**UNITED STATES DEPARTMENT OF COMMERCE**  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/043,933 03/30/98 BALLOUL

J 017753-094

HM22/0804

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EXAMINER

SALIMI, A

ART UNIT

PAPER NUMBER

1643

DATE MAILED:

08/04/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/043,933

Applicant(s)  
Balloul et al

Examiner  
ALI R. SALIMI

Group Art Unit  
1645



☒ Responsive to communication(s) filed on Jun 7, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire Three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-21 and 23-31 is/are pending in the application.

Of the above, claim(s) 10-20 and 25-31 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-9, 21, 23, and 24 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Election/Restriction***

Applicant's election with traverse of Group I in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the restriction does not appear to make any sense. In addition applicants assert that they are dismayed at the level of attention reflected in the action. This is not found persuasive because as was clearly conveyed in the previous Action the invention of Group I is known in the prior art as evidenced by ZHOU et al (1991) wherein the reference teaches a fusion protein of late protein of papillomavirus and early protein of papillomavirus (L1 and E4) see Fig. 1 and page 252, left column. The cited evidence proves that the technical feature of Group I **does not make a contribution over the prior art**. Thus, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 as such the restriction is proper. Moreover, if Applicants are "dismayed" for any particular reason, they can always petition the restriction requirements. In addition, after further review, claims 23, and 24 have been rejoined since the search would not be burdensome. Hence, claims **1-9, 21, 23, 24** have been considered.

The requirement is still deemed proper and is therefore made FINAL.

Claims 10-20, 25-31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected group, the requirement having been traversed in Paper No. 8. Applicant is reminded to cancel the claims to non-elected group(s).

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***Priority***

An application in which the benefits of an earlier application are desired must contain a specific reference to the earlier filed application(s) in the first sentence of the specification (37 CFR 1.78). Please insert, "This is a rule 371 application based on the priority date of PCT/FR97/01412 filed July 29, 1997."

***Specification***

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

***Claim Rejections - 35 USC § 112***

Claims 5, 8, 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5, 8, 9 are confusing and unclear for recitation of "according to one of claim --- wherein" this phrase does not make any sense. Please clarify.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-9, 21, 23, 24 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Lowy et al (US patent No. 5,855,891).

Lowy et al disclosed a composition of papillomavirus late protein in combination to an early protein (see claims 1-10). In addition, they disclosed that the late papillomavirus product can comprise full or fragment fusion partner such as E6, or E7 (see column 4, lines 34-61), as well as co-stimulatory molecules such as B7 (see column 8, lines 3-13). They further disclosed a method of treating and therapeutic immunity of the chimeric peptides (see column 15, Example 11, and 12, and column 16, Example 13). The teaching of Lowy et al meets the limitations of the claimed invention.

Claims 1-9, 21, 23, 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Lowy et al (US patent no. 5,618,536, 4/8/97).

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Lowy et al disclosed a composition of papillomavirus late protein in combination to an early protein (see claims 1, 5, 7-10, 13, 15). In addition, they disclosed that the late papillomavirus product can comprise full or fragment fusion partner such as E6, or E7 (see column 4, lines 39-40), as well as co-stimulatory molecules such as B7 (see column 8, lines 3-13). The teaching of Lowy et al meets the limitations of the claimed invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-9, 21, 23, 24 are rejected under 35 U.S.C. 102(a) as being anticipated by Lowy et al ( WO 96/11274, 4/18/96).

The disclosure of the above cited patent anticipates the claimed invention. The above cited patent disclosed a composition comprising of early and late proteins of papillomavirus to be utilized for treatment and prevention of papillomavirus (see claims 1-15, 21, 22). In addition, they disclosed additional partners that can be present to enhance immuno activity such as B7 (see page 7, lines 29-36).

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Zhou et al (1991).

Zhou et al construct of early and late protein of human papillomavirus type 16 (HPV-16) (see page 251, left column, first full paragraph) meets the limitations of the claim.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 21, 23, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhou et al (Virology, 1991), in view of Heck et al (PNAS USA, 1992) and Robinson et al (WO 94/24267, 1994).

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The claims are directed to a pharmaceutical composition comprising proteins of early and late proteins of human papillomavirus. The composition also is directed to proteins of early and late genes of human papillomavirus and at least one polypeptide having immunostimulatory activity. Furthermore, the claims are directed to a composition of at least one polypeptide from the early or late region and at least one polypeptide having immunostimulatory activity. In addition, the claims are directed to the early genes consisting of E6 or E7, and immunostimulatory molecule selected from well known interleukines or B7-1 or B7-2.

Zhou et al disclosed a production of early and late proteins of human papillomavirus (see Figure 1 "pLC202" construct). In addition they disclosed the utilization of the composition in production of vaccine (see abstract). This differs from the claims since they did not use co-stimulatory molecules.

Heck et al disclosed a series of chimeric proteins consisting of segments of HPV-16 E7 protein and defined the various domains of the E7 that were responsible for the different biological and biochemical properties (see abstract). This differs since they did not fuse the late protein to early protein, and did not use a co-stimulatory molecule.

Robinson et al disclosed that the administration of target antigen and a co-stimulatory factor would induce a strong immune response for treatment of viral infection (see page 8, lines 25-30). They further cited the papillomavirus as a possible virus (see page 4, lines 16-17), and disclosed specific co-stimulatory molecules ( see page 6 lines 11-13). This differs since they did not fuse late and early papillomavirus proteins.



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Therefore, one of ordinary skilled in the art would have been motivated by the teaching of above cited art to produce an effective vaccine for treatment of papillomavirus. The above art teaches the fusion of late and early protein to be utilized as a vaccine (Zhou et al), in addition the above art teaches the domains of the derived proteins which are nononcogenic variant from E7 of human papillomavirus (Heck et al), in addition they teach utilization of co-stimulatory molecules such as B7-1, and B7-2 to enhance immune response against papillomavirus (Robinson et al). The above cited art provide teaching, and motivation for one of ordinary skilled in the relevant art to fuse a late and early proteins or variant of the early protein in addition to a co-stimulatory molecule to generate a vaccine against papillomavirus. The ordinary skilled artisan being familiar with the above cited articles would not have anticipated any unexpected results. Thus the invention as a whole is considered to be *prima facie* obvious absent unexpected results.

No claims are allowed.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Salimi whose telephone number is (703) 305-7136. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Eiseneshenk, can be reached on (703) 308-0452. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ali R. Salimi

8/3/99